DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 21, 2010 has been entered.

Response to Amendment

2. This office action is responsive to the amendment filed on April 21, 2010. As directed by the amendment: claims 1 and 19 have been amended, no claims have been cancelled, and no new claims have been added. Thus, claims 1-32 are presently pending in this application.

Claim Objections

3. Claim 1 is objected to because of the following informalities: "configured to provide independently pathways" seems to be grammatically incorrect. For the purposes of examination, it is interpreted as "independent" pathways. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-8 and 12-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Blomquist et al. (US 20030163090).

6. Regarding claims 1-8 and 12-17, Blomquist et al. discloses an infusion device 10 (fig. 1-4), comprising: a casing comprising an external wall 14 (fig. 4) and a plurality of internal adjoining housings (battery chamber 114, cartridge chamber 80, and remaining chamber defined between for electronics and pump, see fig. 4), including a first housing 80 (fig. 4) enclosing a liquid reservoir 220 (see fig. 11; par. 0058) and a drive mechanism 88 (fig. 4; par. 0058); an electronics assembly (boards 450, 452, fig. 35; par. 0116) and a pump assembly 118 (fig. 4) provided in a second housing (remaining housing between 114 and 80, fig. 4) for controlling the drive mechanism to dispense the liquid from the reservoir according to a selected pattern; a battery (par. 0060) provided in a third housing 114 (fig. 4); and a primary vent 36 (fig. 2) provided for venting the infusion device to atmosphere (par. 0056), said primary vent comprising a hydrophobic barrier (par. 0056) allowing passage of gas therethrough while preventing passage of liquid therethrough (par. 0056); and at least one secondary vent 108 (fig. 4) for venting the infusion device to atmosphere (via venting through primary vent 36) provided between selected ones of said housings (par. 0059; between cartridge chamber 80 and interior of pump housing); said at least one secondary vent including a hydrophobic barrier (par. 0059) allowing passage of gas therethrough while preventing passage of

liquid therethrough (par. 0059); wherein each of said primary and said secondary vents are configured to provide independently pathways to vent the infusion device to atmosphere (par. 0056 describes vent 36 venting to atmosphere; furthermore, vent 108 is *configured to* vent independently to atmosphere in a configuration such as shown in fig. 2, when the casing is removed); said liquid reservoir contains insulin (par. 0003, pumps may be used to deliver insulin; par. 0112, this pump delivers insulin); said liquid reservoir defines a syringe (see fig. 10-11), comprising a generally tubular liquid storage section 202 (fig. 10) and a movable plunger 258 (fig. 9-10); said drive mechanism comprises a lead screw and a drive nut (par. 0064); said second housing is vented to atmosphere via said secondary vent (110 allows passage of gas between chamber 80 and interior of pump housing, par. 0059) and said first housing (first housing 80 having opening 28 when pump cap 16 is removed, par. 0054, 0059; fig. 1-4); means for a user to access said first housing (pump cap 16, fig. 1); means for a user to access said third housing (battery cap 24, fig. 1); said second housing is inaccessible by a user (there is no opening provided into the remaining chamber, see fig. 1); said casing is portable (via belt clip 850, fig. 36-37; par. 0136); said liquid reservoir is refillable (see par. 0072-0073; the reservoir is designed to be filled or refilled by a user); said liquid reservoir is replaceable (see par. 0079, reservoir is capable of being inserted and removed, and is capable of being replaced); said casing is configured to be concealed on a user (via attachment to a belt with belt clip 850, par. 0136; fig. 36-37); said secondary vent is provided between said second housing and said first housing (par. 0059); and said drive

mechanism extends from said first housing to said second housing via an opening (par. 0059) comprising a seal (par. 0062).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blomquist in view of Toner et al. (US 6562616).

9. Regarding claims 9-11, Blomquist discloses the apparatus as claimed except for said hydrophobic barriers comprise membranes, each said membrane having a pre-selected minimum water entry pressure higher than a water pressure of a selected depth of water and greater than or equal to approximately 10 psi. However, Toner et al. teaches hydrophobic membranes include membranes which are impermeable to water up to a certain pressure differential across the membrane (col. 13, ln. 66 - col. 14, ln. 8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Blomquist apparatus such that said hydrophobic barriers comprise membranes, each membrane having a pre-selected minimum water entry pressure higher than a water pressure of a selected depth of water, as taught by Toner et al., since membrane materials having these characteristics can be easily obtained commercially or prepared using standard techniques (col. 14, ln. 6-8).

10. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a membrane with a pre-selected minimum water entry pressure of greater than or equal to 10 psi, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

11. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blomquist in view of Lorenzen et al. (US 6770067).

12. Regarding claim 18, Blomquist discloses the apparatus as claimed except for said first, second, and third housings are hermetically sealed from one another against passage of liquid therebetween. However, Lorenzen et al. teaches hermetically sealing the different compartments within a pump housing (col. 6, ln. 34-47). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Blomquist apparatus such that said first, second, and third housings are hermetically sealed from one another against passage of liquid therebetween, as taught by Lorenzen et al., for the purpose of protecting the critical components of the pump from exposure to dangerous environmental conditions.

13. Claims 19-26, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blomquist in view of Moberg (US 6248093).

14. Regarding claims 19-26, 30, and 31, Blomquist discloses the apparatus as claimed (see elements identified in the rejections of claims 1-8 and 12-17 above), including a primary vent 36 (fig. 2) for venting the casing to the atmosphere, except for a

plurality of primary vents for venting the casing to the atmosphere. However, Moberg teaches utilizing multiple primary vent ports in two different locations (col. 8, ln. 10-32 describe different possible locations for a vent port, and ln. 30-32 describe utilizing them in both locations at once). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Blomquist apparatus such that it comprises a plurality of primary vents, as taught by Moberg, for the purpose of further decreasing the chance of harmful differential pressures building up inside the device (col. 7, ln. 38-49).

15. Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blomquist in view of Moberg, and further in view of Toner et al.

16. Regarding claims 27-29, Blomquist in view of Moberg discloses the apparatus as claimed except for said hydrophobic barriers comprise membranes, each said membrane having a pre-selected minimum water entry pressure higher than a water pressure of a selected depth of water and between about 10 psi and about 15 psi. However, Toner et al. teaches hydrophobic membranes include membranes which are impermeable to water up to a certain pressure differential across the membrane (col. 13, ln. 66 - col. 14, ln. 8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Blomquist in view of Moberg apparatus such that said hydrophobic barriers comprise membranes, each membrane having a pre-selected minimum water entry pressure higher than a water pressure of a selected depth of water, as taught by Toner et al., since membrane

materials having these characteristics can be easily obtained commercially or prepared using standard techniques (col. 14, ln. 6-8).

17. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a membrane with a pre-selected minimum water entry pressure between about 10 psi and about 15 psi, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller,* 105 USPQ 233.

18. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blomquist in view of Moberg, and further in view of Lorenzen et al.

19. Regarding claim 32, Blomquist in view of Moberg discloses the apparatus as claimed except for said reservoir housing, said electronics and mechanical housing, and said battery housing are hermetically sealed from one another against passage of liquid therebetween. However, Lorenzen et al. teaches hermetically sealing the different compartments within a pump housing (col. 6, ln. 34-47). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Blomquist in view of Moberg apparatus such that said reservoir housing, said electronics and mechanical housing, and said battery housing are hermetically sealed from one another against passage of liquid therebetween, as taught by Lorenzen et al., for the purpose of protecting the critical components of the pump from exposure to dangerous environmental conditions.

Response to Arguments

20. Applicant's arguments filed July 9, 2009 have been fully considered but they are not persuasive.

21. In response to applicant's argument that the newly added limitation "wherein each of said primary and secondary vents are configured to provide independently pathways to vent the infusion device to atmosphere", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

22. In Blomquist's case, it is clear that vent 36 provides a path to atmosphere (par. 0056). Furthermore, vent 108 is *configured to* provide an independent vent path to atmosphere under conditions where the external case has been opened, such as shown in fig. 2. Therefore, the structure of Blomquist is capable of performing the claimed intended use.

Conclusion

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN R. PRICE whose telephone number is (571)270-5421. The examiner can normally be reached on Monday-Thursday, 9:00 a.m. - 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 3763

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